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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,749	06/25/2001	Jordan L. Holtzman	11909.1USWO	2030

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MERCHANT & GOULD PC
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER	
HAYES, ROBERT CLINTON	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/830,749	Holtzman
Examiner	**Art Unit**
Robert C. Hayes, Ph.D.	1647

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 27, 2003* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above, claim(s) *4-37* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-3* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-37* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I (claims 1-3; as it relates to animal *B*-amyloid 1-42) in Paper No. 8 is acknowledged. The traversal is on the ground(s) that "a search could be efficiently done encompassing Groups I-V without burdening the Examiner", and that all groups and claims "form a single general inventive concept under PCT Rule 13.1". This is not found persuasive because PCT Rule 13 does not provide for multiple products or methods within a single application, in which each of the separable groups require their own unique products, and/or involve different methods with different goals and/or starting materials and/or protocols. Moreover, because the special technical features of the Group II-V inventions are not present in the Group I claims, unity of invention is lacking, and therefore, would also be an undue search burden on the Examiner for the art recognized distinct subject matter. The requirement is still deemed proper and is therefore made FINAL.

Claims 4-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Claim Rejections - 35 U.S.C. § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Page 6 of the specification states that "[c]haperones are, in general, well studied and/or characterized proteins", that "[w]ell characterized features of numerous chaperones include the genes encoding them...", and that "[a]s used herein, Q2 refers to any of the common names for this protein, including TPDO-Q2, Erp57, and Grp58 *and all naturally occurring variant forms of this protein*... [emphasis added]". Page 5 of the specification states that "[a]myloid precursor protein, β-amyloid, and various fragments of β-amyloid have been characterized", that "[k]nown features of amyloid precursor protein and β-amyloid include *mammalian* genes encoding them", and that "β-Amyloid can be made and/or isolated in *a variety of forms* [emphasis added]". However, not a single amino acid sequence of any Q2 or β-amyloid protein, nor gene sequence encoding such, is provided in the instant specification. Nor does the specification provide a single reference that defines such; especially as it relates to the genus of "animal" β-amyloid proteins required in the claimed protein complex. In other words, the record is currently devoid of sufficient "[w]ell characterized features" to describe the Q2 and β-amyloid proteins required to make the claimed product "complex comprising Q2 and β-amyloid"; thereby, not currently meeting the written description requirements under 35 U.S.C. 112, first paragraph.

Second, the open-ended definition for "animal" β-amyloid "in a variety of forms" on page 5 of the specification, as well as the open-ended definition on page 6 of the specification for Q2 to encompass "all naturally occurring variant forms of this protein...", fails to allow the skilled artisan to reasonably visualize or predict what critical amino acid residues would structurally characterize the genus of "variant" Q2 or β-amyloid polypeptides, or "animal β-amyloid polypeptides", as encompassed by the claims, because it is unknown and not described what structurally constitutes such generic Q2 or β-amyloid polypeptides. Thus, the written description requirements under 35 U.S.C. 112, first paragraph are further not met.

Applicant is directed toward the Revised Interim Utility and Written Description Guidelines, Federal Register, Vol.64, No.244, pages 71427-71440, Tuesday December 21, 1999.

3. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to a structurally definable chaperone Q2 and β-amyloid polypeptide complex, does not reasonably provide enablement for any complex comprising biologically functional equivalent forms of Q2 or β-amyloid with no known or recited structural and functional characteristics. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The name, "Q2" or "β-amyloid", alone, does not sufficiently characterize and enable the full scope of the polypeptides encompassed by the current claim language, because the inclusion

of any biological functional equivalent protein, which exists "in a variety of forms" or encompasses "variant forms", etc. within the definition of Q2 or β-amyloid proteins sets forth little structural and functional characteristics. Importantly, the specification does not teach which particular amino acids are critical for a generic Q2 or β-amyloid protein's function; nor how to distinguish Q2 or β-amyloid variants encompassed by the instant invention from any different Q2- or β-amyloid- related polypeptides that possesses none of the desired functions of the instant invention. Therefore, any such broadly claimed polypeptides without definable structural and functional characteristics, and which alternatively encompass randomly mutated Q2- or β-amyloid- related polypeptides, would be expected by the skilled artisan to result in inactive proteins. For example, Rudinger states on page 3 that "it is impossible to attach a unique significance to any residue in a sequence. A given amino acid will not by any means have the same significance in different peptide sequences, or even in different positions of the same sequence". Rudinger further states on page 6 that "the significance of particular amino acid sequences for different aspects of biological activity cannot be predicted *a priori* but must be determined from case to case by painstaking experimental study". Therefore, the lack of guidance provided in the specification as to what minimal structural requirements are necessary for a functional Q2 or β-amyloid polypeptide complex would prevent the skilled artisan from knowing how to make and use the instant invention, especially as it relates to determining whether any random modification or mutation to such polypeptides could be made which retains the desired function of the instant invention, because any random mutation or modification

manifested within a Q2 or β-amyloid protein would be predicted to adversely alter the biologically active 3-dimensional conformation of such, without requiring undue experimentation to determine otherwise.

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

RCH

Robert C. Hayes, Ph.D.
April 17, 2003

Gary d. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600